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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,124	12/31/2003	Scott Umlauf	036481-0146	1736

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EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/748,124	Applicant(s) UMLAUF, SCOTT	
	Examiner Brian Whiteman	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27,30,33,38,39 and 42-49 is/are pending in the application.
- 4a) Of the above claim(s) 42-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27,30,33,38 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/31/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/30/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Non-Final Rejection

Claims 27, 30, 33, 38, 39, and 42-49 are pending.

The cancellation of claims 1-26, 28-29, 31-32, 34-37 and 40-41 and the addition of claims 42-49 in paper filed on 3/3/06 is acknowledged and considered by the examiner.

Election/Restrictions

Applicant's election of Group IV (species TRANCE) in the reply filed on 3/3/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Upon a search of the prior art, the non-elected species in claim 27 will be rejoined with the elected. Thus, the election of species requirement is withdrawn.

New claims 42-49 read on an invention set forth in Group II (which was non-elected). See election/restriction mailed on 12/6/05. The claims encompassed in the invention of Group II were cancelled by applicant and added in new claims 42-49. Applicant did not traverse the restriction. Thus, the new claims are withdrawn. In addition, the recitation of at least one peptide antigen indicates that the claim 27 is limited to at least one antigen. Thus, claims 42-49 would not further limit claim 27.

Claims 42-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 3/3/06.

Priority

Listing parent application 09/705,022 filed on 11/01/2000 and provisional application 60/163,195 filed on 11/03/99 on an application data sheet filed on 12/31/03 is acknowledged.

Claim Objections

Claims 33 and 38 are objected to because of the following informalities: the phrase "a vaccine composition according to claim" is an improper phrase for a dependent claim. Suggest replacing the phrase with -- the vaccine composition according to claim --.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 27 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuby (*Immunology*, 2nd ed. W.H. Freeman Company, pp. 19-20, 89-90, 103-106 and 297, 1994) taken with Mendoza et al. (A40). Kuby teaches that the general properties of antigens can stimulate an immune response to viral and bacterial infections, thus triggering the body's most effective defense mechanism against infectious disease (pp. 103-106). In addition, Kuby teaches that adjuvants (e.g. cytokines) combined with an antigen and injected with it serve to enhance the immunogenicity of that antigen (pg. 89-90). For example, adjuvants are often used to boost the immune response when an antigen has low immunogenicity or when only small amounts of antigen are available, limiting the immunizing dosage (pg. 90). However, Kuby does not specifically teach making and using an immunogenic composition comprising at least one peptide antigen and an expression vector comprising a polynucleotide encoding CD40L.

However, at the time the invention was made, Mendoza reports that some studies indicate that injection of a DNA vaccine along with a plasmid vector encoding an immune stimulatory cytokine, such as interleukin-2 (IL-2) or mouse granulocyte-macrophage CSF, could induce a greater antibody or Th cell response against the target antigen than injection of plasmid encoding the antigen alone (pg. 5777). In addition, Mendoza indicates that a plasmid encoding CD40L can serve as a genetic adjuvant capable of augmenting humoral and cellular immune responses to antigens encoded by plasmid DNA expression vectors (abstract).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Kuby taken with Mendoza, namely to make and use an immunogenic composition comprising at least one peptide antigen and a polynucleotide encoding a cytokine (e.g. CD40L). One of ordinary skill in the art would have

been motivated to combine at least one peptide antigen and an expression vector comprising a polynucleotide encoding a cytokine consisting of CD40L to enhance an immune response against the target antigen by coinjecting a plasmid vector encoding an immune stimulatory cytokine as taught by Mendoza.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 27 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuby taken with Mendoza as applied to claims 27 and 33 above, and further in view of either Chen et al. (A26) or Wong et al. (A56).

However, Kuby taken with Mendoza do not specifically teach making and using an immunogenic composition comprising at least one peptide antigen; and an expression vector encoding at least one cytokine selected from either TRANCE or flt-3L.

However, at the time the invention was made, Chen reports anti-tumor activity by flt3-L is consistent with its known stimulatory effect on antigen-presenting cells. In addition, Chen produces a retroviral vector encoding the flt-3L ligand (abstract).

In addition, at the time the invention was made, Wong reports that TRANCE enhances immune system cells by promoting the life span of mature dendritic cells (pg. 2078).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Kuby taken with Mendoza in further view of either Chen or Wong, namely to make and use an immunogenic composition comprising at least one peptide antigen and a polynucleotide encoding at least one cytokine selected from the group

consisting of TRANCE (Wong) or flt-3L (Chen). One of ordinary skill in the art would have been motivated to combine at least one peptide antigen and an expression vector comprising a polynucleotide encoding at least one cytokine selected from the group consisting of TRANCE or flt-3L to enhance an immune response against the target antigen by coinjecting a plasmid vector encoding an immune stimulatory cytokine as taught by Mendoza, Chen and Wong.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 27, 30, 33, 38, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuby taken with Mendoza and either Chen or Wong as applied to claims 27 and 33 above, and in further view of Lai (A34).

However, Kuby taken with Mendoza in further view of either Chen or Wong do not teach coating onto a core carrier the immunogenic composition comprising of at least one peptide antigen and an expression vector comprising a polynucleotide encoding at least one cytokine selected from the group consisting of CD40L, TRANCE, or flt-3L and administering the composition to elicit an immune response.

However, at the time the invention was made, Lai mentions that a technique called biolistic transformation (biological ballistic system) microparticle injection, gene gun, or particle bombardment is rapid and specific for genetic immunization (abstract). The basic idea of this technique is that DNA or biological material coated onto heavy tungsten or gold particles is shot into target cells or animals (abstract). Lai expressed an antigen in a plasmid vector and introduced the vector into mice through two methods: (i) using a hand-held form of the biolistic

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system that can propel DNA-coated gold microprojectiles directly into the skin; (ii) using a conventional intramuscular injection of DNA into quadricep muscles of transfected mice (abstract). Both delivery systems induced humoral and cellular immunity in the experimental mice. In addition, Lai conducts trials in mice by injecting intramuscularly (i.m.) or gene gun administration a total of four injections at 2-week intervals or a total of three injections at intervals of 2 weeks, respectively (pg. 644-45); indicating a prime and booster administration of the immunogenic composition.

It would have been *prima facie* obvious for a person of ordinary skill in the art at the time the invention was made to coat the immunogenic composition of the combined cited references as indicated above onto heavy tungsten or gold for transdermal delivery into a vertebrate subject using a gene gun. One of ordinary skill in the art would have been motivated to have employed the microparticle injection, gene gun, or particle bombardment wherein a metal particle is employed as a core carrier for delivering the immunogenic composition of the combined cited references because using a gene gun for genetic immunization saves time, money and labor, as taught by Lai.

Furthermore, it would have been obvious for a person of ordinary skill in the art to provide a prime and booster administrations of the immunogenic composition of the combine cited references in a vertebrate subject. One of ordinary skill in the art would have been motivated to have employed prime and booster administrations of the immunogenic composition in the subject because Lai teaches that the combination use of prime and booster administrations of an immunogenic composition would elicit a maximum immune response of a treated subject to a targeted antigen.

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Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE – Art Unit 1635, can be reached at (571) 272-0811.

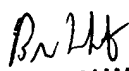
Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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